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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,087	BACHMANN ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-51 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28 and 50-51, drawn to compositions of a product, classified in class 424, subclass 193.1. (Claim 51 is included because it is interpreted as a product claim; its intended use, "for the manufacture of a medicament for treatment of Alzheimer ('s) and related diseases", is given no patentable weight.)

II. Claims 29-44, drawn to vaccines, classified in class 424, subclass 204.1.

III. Claim 45, drawn to a method of making a product, classified in class 436, subclass 543.

IV. Claims 46-49, drawn to methods of immunization, classified in class 424, subclass 184.1.

Election of Species

For each of invention sets I-IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of **inventions** I-IV and one of inventions (A)-(L) and (M)-(P). Restriction also requires election to one of their corresponding subgroups if applicable.

(A)-(L) of Claim 2 are a group in which the core particle is selected from:

(A) a virus;

(B) a virus-like particle;

Recombinant proteins listed as (b1) Hepatitis B virus; (b2) measles virus; (b3) Sindbis virus; (b4) Rotavirus; (b5) Foot-and-Mouth-Disease virus; (b6) Retrovirus; (b7) Norwalk virus; (b8) Alphavirus; (b9) human Papilloma virus; (b10) Polyoma virus; (b11) bacteriophages; (b12) RNA-phages; (b13) Ty; (b14) Qβ-phage; (b15) GA-phage; (b16) fr-phage; (b17) AP205 phage; and (b18) fragments of (b1)-(b17).

(C) a bacteriophage;

Bacteriophages listed as (c1) Qβ; (c2) R17; (c3) fr; (c4) GA; (c5) SP; (c6) MS2; (c7) M11; (c8) MX1; (c9) NL95; (c10) f2; (c11) PP7; and (c12) AP205.

(D) a virus-like particle of a RNA-phage;

(E) a bacterial pilus;

(F) a viral capsid particle;

Coat proteins of RNA phages listed as (f1) SEQ ID NO:4; (f2) a mixture of SEQ ID NO:4 and SEQ ID NO:5; (f3) SEQ ID NO:6; (f4) SEQ ID NO:7; (f5) SEQ ID NO:8; (f6) SEQ ID NO:9; (f7) a mixture of SEQ ID NO:9 and SEQ ID NO:10; (f8) SEQ ID NO:11; (f9) SEQ ID NO:12; (f10) SEQ ID NO:13; (f11) SEQ ID NO:14; (f12) SEQ ID NO:15; (f13) SEQ ID NO:16; and (f14) SEQ ID NO:28.

(G) recombinant form of a virus;

(H) recombinant form of a virus-like particle;

(I) recombinant form of a bacteriophage;

(J) recombinant form of a virus-like particle of a RNA-phage;

(K) recombinant form of a bacterial pilus; and

(L) recombinant form of a viral capsid particle.

Mutant coat proteins of RNA phages listed as (f1)-(f14) above in which at least one lysine residue is modified by: (I1) removal by way of substitution; (I2) addition by way of substitution; (I3) removal by way of deletion; and (I4) addition by way of insertion.

Inventions (A)-(L) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent different structural forms of viruses, derived from separate

types of organisms (e.g. bacterial vs. mammalian). Additionally, they function via different mechanisms. Therefore, inventions (A)-(L) are distinct. The examination of inventions (A)-(L) would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Claims 19, 20, 21, 24, 25, 26, 27, 28, 40, 41, 42, 43 and 44 define the mode of chemical association between the core and antigen or antigenic determinant.

(M) covalent bond;

(N) non-peptide bond;

(O) fusion; and

(P) amino acid linker

Amino acid linkers listed in Claims 26, 27, 42 and 43 are: (p1) GGC; (p2) GGC-CONHs; (p3) GC; (p4) GC-CONH2; (p5) C; (p6) C-CONH2; and (p7) SEQ ID NO:77.

Inventions (M)-(P) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent separate modes of chemical association between the core and antigen or antigenic determinant, and each display differential interatomic characteristics and properties. Therefore, inventions (M)-(P) are distinct. The examination of inventions (M)-(P) would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

INVENTIONS I-IV

The composition of Group I and the vaccine composition of Group II are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the compositions do not overlap the scope of the vaccine composition claims and vice versa as evidenced by the distinct compositions or designs and functions of the claimed invention. The vaccine "comprises a conventional saline or

buffered aqueous solution medium in which the composition of the present invention is suspended or dissolved." Furthermore, the vaccine's function is to provoke an immune response *in vivo*. See Specifications, page 26. In contrast, the composition according to the claims of Group I comprise a core particle and an antigen or antigenic determinant. Functionally, the composition is useful as a single ingredient in the production of vaccines. Thus, by virtue of the different compositions and functions of the invention of Groups I and II, these related inventions are distinct.

Inventions from Groups I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make a materially different product such as other protein types of variable functions. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the composition may be used in a materially different process, for example, as use as an

affinity reagent in protein purification. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated as proper.

Inventions from Groups II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make a materially different product such as other protein types of variable functions. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the composition may be used in a materially different process, for example, as use as an affinity reagent in protein purification. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated as proper.

Inventions III and IV are directed to related products but differential processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions III-VI are methods with different modes of operation, with respect to starting materials, protocol procedures, and end products; therefore, each method is patentably distinct. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

CONCLUSION

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning, Ph.D.
Patent Examiner

4/15/06

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